REMARKS

Claims 1 to 15 as set forth in Appendix II of this paper are currently pending in this case. Claims 1 and 15 have been amended as indicated in the Listing of Claims set forth in Appendix I of this paper.

Accordingly, applicants have revised the wording of stage (a) in Claim 1 to provide antecedent basis for the expression *"additionally used solvents"* in stage (b), and have effected some editorial changes in the wording of stage (b). Claim 15 has been revised to relate to a human food, a pharmaceutical or an animal feed which contains the carotenoid-containing dry powder. No new matter has been added.

The Examiner has rejected Claim 15 under Section 101 for being drawn to a "use" without specifying the requisite process involved in the use. Withdrawal of the rejection is solicited in light of the changes made by applicants in the wording of Claim 15.

The Examiner has further rejected Claim 15 under Section 112, ¶1, contending that the claimed invention is not supported by either a specific or a substantial asserted utility or a well established utility. More particularly, the Examiner contends that *"one skilled in the art clearly would not know how to use the claimed invention"*.

Favorable reconsideration of the Examiner's position and withdrawal of the respective rejection is respectfully solicited. On the one hand, applicants have addressed the well known utilization of carotenoid dry powders as colorants at the outset of the specification[1]. On the other hand, each of the prior art references which are applied by the Examiner under Section 103(a) mention the same conventional utility[2]. The Examiner's assertion that *"one skilled in the art clearly would not know how to use the claimed invention"* is in light thereof not deemed to be well taken. Favorable action is solicited.

---

1) For example, page 1, indicated lines 27 to 31, and indicated lines 33 to 41, as well as the paragraph bridging page 1 and page 2, and page 11, indicated lines 7 to 12, of the application.

2) For example, ***Dobler et al.***: page 2, indicated line 13 et seq., and page 4, indicated line 34 et seq., of ***WO 96/01570***; ***Horn et al.***: col. 1, indicated line 10 et seq., of ***US 4,522,743***; and ***Jensen et al.***: page 8, indicated line 1 et seq., of ***WO 91/06292***.

The Examiner has rejected Claims 1 to 14 under 35 U.S.C. §103(a) as being unpatentable in light of the teaching of ***Dobl r et al.*** (WO 96/01570) taken alone or taken in view of the disclosure of ***Horn et al.*** (US 4,522,743).

Applicants' invention relates to a process for producing a dry powder of one or more carotenoids wherein the carotenoid(s) are initially dispersed and subsequently dried in the presence of a combination of lactose and at least one soybean protein. Applicants have found that the utilization of the combination of lactose and at least one soybean protein provides the resultant product with a number of particular and advantageous properties. As illustrated by Example 1 and the Comparative Example[3] the dry powder obtained in accordance with applicants' process has a significantly improved color strength and bio-availability when compared with a corresponding dry powder which is prepared in the same manner but using glucose syrup instead of lactose. The experiments further show that the the dry powder obtained in accordance with applicants' process has a considerably higher apparent density than the comparison product. The reduction in "intermediate space" between the powder particles obtained by applicants' process contributes to a higher stability of applicants' powders. Additionally, applicants' powders form, upon re-dispersion, systems which are less prone to colloidal instability, flocculating or sedimentation of particles, or "creaming"[4].

The teaching of ***Dobler et al.*** relates to water dispersible dry powders of vitamins and/or carotenoids which are obtained by a process in which partially degraded soybean proteins are used as protective colloids. ***Dobler et al.*** further provides that other conventional auxiliaries such as sugars, sugar alcohols, starch or starch derivatives, stabilizers and emulsifiers may be added. Exemplary preparations disclosed by ***Dobler et al.*** comprise glucose syrup, and the Examiner takes the position that a person of ordinary skill in the art would have been motivated -either by the technical background knowledge or by the teaching of ***Horn et al.***- to replace the glucose syrup by lactose with the expectation that glucose syrup and lactose are equivalent and provide for similar results.

---

3) Page 11, indicated line 17, to page 12, indicated line 33, of the application.

4) Page 2, indicated lines 31 to 45, in conjunction with page 3, indicated lines 34 to 38, of the application.

However, as shown by the results of applicants' comparative experiment and addressed in the foregoing, the expectation of similar results in not met when glucose syrup is replaced by lactose. To the contrary, the utilization of lactose in combination with the soybean proteins distinctly improves a number of properties of the product, namely its color strength, its bio-availability and its stability. As conceded by the Examiner, a person of ordinary skill in the art regarded glucose syrup and lactose as equivalent when applicants made their invention, and expected to arrive at similar results.

It is well settled that the invention as a whole which is referenced in Section 103(a) embraces not only the subject matter particularly recited in the claims, but also the properties and results of such subject matter which arise from the claimed combination and are disclosed in the specification[5]. Since the unexpected and advantageous properties which arise from the particular combination of requirements set forth in the claims could not be expected, the teaching of ***Dobler et al.*** when taken in view of the technical background knowledge or in view of the teaching of ***Horn et al.*** cannot be considered to render applicants' invention *prima facie* obvious within the meaning of 35 U.S.C. §103(a). Although the foregoing argument essentially focuses on the provisions set forth in Claim 1 and the properties of the product defined in Claim 10, the argument is equally applicable where the subject matter of Claims 2 to 9 and 11 to 15 is concerned since these claims depend either directly or indirectly upon Claim 1 and Claim 10 and therefore incorporate the essential requirements by reference[6]. Favorable reconsideration of the Examiner's position and withdrawal of the rejection of Claims 1 to 14 on the basis of ***Dobler et al.*** when taken alone or in view of ***Horn et al.*** is therefore respectfully solicited.

The Examiner has rejected Claims 1 to 4, 6, 7 and 9 to 14 under 35 U.S.C. §103(a) as being unpatentable in light of the teaching of ***Jensen et al.*** **(WO 91/06292)** taken alone or taken in view of the disclosure of ***Horn et al.*** **(US 4,522,743)**.

---

5) ie. In re Antonie, 559 F.2d 618, 195 USPQ 6 (CCPA 1977); In re Wright, 848 F.2d 1216, 6 USPQ2d 1959 (Fed. Cir. 1988), overruled on other grounds in In re Dillon, 919 F.2d 688, 16 USPQ2d 1897 (Fed. Cir. 1990) (en banc), cert. denied 500 U.S. 904 (1991)

6) If an independent claim is non-obvious under 35 U.S.C. §103, then any claim depending therefrom is non-obvious (In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)).

Jensen t al. disclose a process for preparing water dispersible solid powders of inter alia carotenoids wherein a variety of hydrocolloids of different origin can be used[7]. ***J nsen t al.*** further mention the addition of conventional excipients such as, inter alia, sorbitol and sucrose to the reaction medium[8] and provide that powdery spraying excipients may be employed in the drying process to avoid agglomeration of the product and adherence of the product to the spraying chamber[9]. Lactose is mentioned by ***Jensen et al.*** solely as one of the powdery spraying excipients.

Exemplary preparations disclosed by ***Jensen et al.*** comprise gelatine as colloid and sucrose as one of the excipients, and the Examiner takes the position that a person of ordinary skill in the art would have been motivated -either by the technical background knowledge or by the teaching of ***Horn et al.***- to replace the sucrose by ie. glucose or lactose with the expectation to arrive at similar results. It could, however, not be expected at the time applicants made their invention that a change in the excipient would distinctly improve properties of the product such as its color strength, its bio-availability and its stability, as indirectly corroborated by the comparative data provided in the application[10]. As such, the teaching of ***Jensen et al.*** when taken alone or taken in view of the teaching of ***Horn et al.*** is insufficient to render applicants' invention <u>as a whole</u> prima facie obvious. Favorable reconsideration of the Examiner's position and withdrawal of the rejection of Claims 1 to 14 on the basis of ***Jensen et al.*** when taken alone or in view of ***Horn et al.*** is therefore respectfully solicited.

The Examiner has rejected Claims 5 and 8 under 35 U.S.C. §103(a) as being unpatentable in light of the disclosure of ***Jensen et al.*** when taken in view of the teaching of ***Dobler et al.*** It is respectfully urged that the foregoing remarks and explanations concerning ***Jensen et al.***'s disclosure and the teaching of ***Dobler et al.*** are fully applicable in this context. Moreover, applicants' comparison of the

7) Page 4, indicated line 35, to page 5, indicated line 9, of ***WO 91/06292***.

8) Page 5, indicated lines 19 to 22, of ***WO 91/06292***.

9) Page 6, indicated line 4 et seq. and indicated line 27 et seq., of ***WO 91/06292***.

10) A direct comparison of ***Jensen et al.***'s process and applicants' process cannot be expected to provide results which are suitable as corroboration because the representative examples disclosed by ***Jensen et al.*** differ from the requirements of applicants' invention not only in the nature of the "excipient" but also in the nature of the hydrocolloid.

process and product according to ***Dobler t al.***'s teaching and the inventive process and product corroborate the significant improvement and the distinct advantage which arises from the particular combination of requirements which is defined in applicants' claims. Favorable reconsideration of the Examiner's position and withdrawal of the respective rejection is therefore respectfully solicited.

In light of the foregoing and the attached, the application should now be in condition for allowance. Early action is appreciated.

REQUEST FOR EXTENSION OF TIME:

It is respectfully requested that a *three* month extension of time be granted in this case. A check for the *$950.00* fee is attached.

Please charge any shortage in fees due in connection with the filing of this paper, including Extension of Time fees, to Deposit Account No. 11.0345. Please credit any excess fees to such deposit account.

Respectfully submitted,
KEIL & WEINKAUF

/HBKeil

Herbert B. Keil
Reg. No. 18,967

1350 Connecticut Ave, N.W.
Washington, D.C. 20036
(202) 659-0100

Encl.: THE LISTING OF CLAIMS (Appendix I)
THE CURRENT CLAIMS (Appendix II)

HBK/BAS

APPENDIX I:

THE LISTING OF CLAIMS (version with markings):

1. (*currently amended*) A process for producing dry powders of one or more carotenoids by

   a) dispersing one or more carotenoids in an aqueous molecular or colloidal solution of a mixture of lactose and a protective colloid, and optionally containing additional solvents, and

   b) converting the dispersion [~~which has~~] formed in step a) into a dry powder by removing the water and[~~, where appropriate, additionally used~~] the optional additional solvents and drying, [~~where appropriate~~] optionally in the presence of a coating material,

   wherein at least one soybean protein is used as protective colloid in process step a).

2. (*original*) A process as claimed in claim 1, wherein the dispersion step a) comprises the preparation of a suspension of one or more carotenoids in an aqueous molecular or colloidal solution of a mixture of lactose and at least one soybean protein.

3. (*original*) A process as claimed in claim 2, wherein the suspension prepared in process step a) is ground before conversion into a dry powder.

4. (*original*) A process as claimed in claim 1, wherein the dispersion in stage a) comprises the following steps:

   a_1) dissolving one or more carotenoids in a water-miscible organic solvent or in a mixture of water and a water-miscible organic solvent or

   a_2) dissolving one or more carotenoids in a water-immiscible organic solvent and

   a_3) mixing the solution obtained as in a_1) or a_2) with an aqueous molecular or colloidal solution of a mixture of lactose and at least one soybean protein, resulting in the hydrophobic phase of the carotenoid as nanodisperse phase.

5. (*previously submitted*) A process as claimed in claim 1, wherein at least one partially degraded soybean protein with a degree of hydrolysis of from 0.1 to 20% is used as protective colloid.

6. (*previously submitted*) A process as claimed in claim 1, wherein the carotenoids used are oxygen-containing carotenoids.

7. (*original*) A process as claimed in claim 6, wherein the oxygen-containing carotenoids are compounds selected from the group consisting of astaxanthin, canthaxanthin, lutein, zeaxanthin, citranaxanthin and ethyl β-apo-8'-carotenoate.

8. (*original*) A process as claimed in claim 7, wherein

   a) astaxanthin and/or canthaxanthin is dissolved in a water-miscible organic solvent or a mixture of water and a water-miscible organic solvent at temperatures above 30°C,

   b) the resulting solution is mixed with an aqueous molecular or colloidal solution of a mixture of lactose and a partially degraded soybean protein with a degree of hydrolysis of from 0.1 to 20%, and

   c) the dispersion which has formed is converted into a dry powder.

9. (*original*) A process as claimed in claim 8, wherein astaxanthin is used as carotenoid.

10. (*previously submitted*) A carotenoid-containing dry powder obtainable by a process as defined in claim 1.

11. (*original*) A dry powder as claimed in claim 10 with a carotenoid content of from 0.1 to 30% by weight.

12. (*previously submitted*) A dry powder as claimed in claim 10, comprising oxygen-containing carotenoids selected from the group consisting of astaxanthin, canthaxanthin, lutein, zeaxanthin, citranaxanthin and ethyl β-apo-8'-carotenoate.

13. (*original*) A dry powder as claimed in claim 12, comprising 5 to 20% by weight of astaxanthin.

14. (*original*) A dry powder as claimed in claim 12, comprising 5 to 20% by weight of canthaxanthin.

15. (*currently amended*) [~~The use of~~] A human food, a pharmaceutical or an animal feed comprising the carotenoid-containing dry [~~powders as~~] powder defined in claim 10 as [~~addition to human foods, pharmaceuticals and/or animal feeds~~] an additive.

APPENDIX II:

THE CURRENT CLAIMS (clean version):

1. (*currently amended*) A process for producing dry powders of one or more carotenoids by

   a) dispersing one or more carotenoids in an aqueous molecular or colloidal solution of a mixture of lactose and a protective colloid, and optionally containing additional solvents, and

   b) converting the dispersion formed in step a) into a dry powder by removing the water and the additional solvents and drying, optionally in the presence of a coating material,

   wherein at least one soybean protein is used as protective colloid in process step a).

2. (*original*) A process as claimed in claim 1, wherein the dispersion step a) comprises the preparation of a suspension of one or more carotenoids in an aqueous molecular or colloidal solution of a mixture of lactose and at least one soybean protein.

3. (*original*) A process as claimed in claim 2, wherein the suspension prepared in process step a) is ground before conversion into a dry powder.

4. (*original*) A process as claimed in claim 1, wherein the dispersion in stage a) comprises the following steps:

   a_1) dissolving one or more carotenoids in a water-miscible organic solvent or in a mixture of water and a water-miscible organic solvent or

   a_2) dissolving one or more carotenoids in a water-immiscible organic solvent and

   a_3) mixing the solution obtained as in a_1) or a_2) with an aqueous molecular or colloidal solution of a mixture of lactose and at least one soybean protein, resulting in the hydrophobic phase of the carotenoid as nanodisperse phase.

5. (*previously submitted*) A process as claimed in claim 1, wherein at least one partially degraded soybean protein with a degree of hydrolysis of from 0.1 to 20% is used as protective colloid.

6. (*previously submitted*) A process as claimed in claim 1, wherein the carotenoids used are oxygen-containing carotenoids.

7. (*original*) A process as claimed in claim 6, wherein the oxygen-containing carotenoids are compounds selected from the group consisting of astaxanthin, canthaxanthin, lutein, zeaxanthin, citranaxanthin and ethyl β-apo-8'-carotenoate.

8. (*original*) A process as claimed in claim 7, wherein

   a) astaxanthin and/or canthaxanthin is dissolved in a water-miscible organic solvent or a mixture of water and a water-miscible organic solvent at temperatures above 30°C,

   b) the resulting solution is mixed with an aqueous molecular or colloidal solution of a mixture of lactose and a partially degraded soybean protein with a degree of hydrolysis of from 0.1 to 20%, and

   c) the dispersion which has formed is converted into a dry powder.

9. (*original*) A process as claimed in claim 8, wherein astaxanthin is used as carotenoid.

10. (*previously submitted*) A carotenoid-containing dry powder obtainable by a process as defined in claim 1.

11. (*original*) A dry powder as claimed in claim 10 with a carotenoid content of from 0.1 to 30% by weight.

12. (*previously submitted*) A dry powder as claimed in claim 10, comprising oxygen-containing carotenoids selected from the group consisting of astaxanthin, canthaxanthin, lutein, zeaxanthin, citranaxanthin and ethyl β-apo-8'-carotenoate.

13. (*original*) A dry powder as claimed in claim 12, comprising 5 to 20% by weight of astaxanthin.

14. (*original*) A dry powder as claimed in claim 12, comprising 5 to 20% by weight of canthaxanthin.

15. (*currently amended*) A human food, a pharmaceutical or an animal feed comprising the carotenoid-containing dry powder defined in claim 10 as an additive.